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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/599,307

09/25/2006

Daniel J. Cosgrove

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EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

NOTIFICATION DATE

DELIVERY MODE

07/30/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patatty@ipmvs.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/599,307	<b>Applicant(s)</b> COSGROVE, DANIEL J.	
	<b>Examiner</b> Anne R. Kubelik	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7, 14, 16-22, 29, 31-37 and 45-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 14, 16-22, 29, 31-37 and 45-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1638

### **DETAILED ACTION**

1. Claims 1-7, 14, 16-22, 29, 31-37 and 45-51 are pending.
2. The reference on the IDS filed 4 April 2009 that is lined out, was done so because no date was provided.
3. The objection to claims 1, 6-7, 16 and 31-51 because of informalities is withdrawn in light of Applicant's amendment of the claims.
4. The rejection of claims 2-3, 14, 17-18 and 29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is withdrawn in light of Applicant's amendment of the claims.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 16, 31-37 and 45-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 7 January 2009, as applied to claims 1, 16, 31-37, 39 and 45-51. Applicant's arguments filed 4 April 2009 have been fully considered but they are not persuasive.

Art Unit: 1638

Neither the instant specification nor the originally filed claims appear to provide support for the recitation of the crop producing a Cry2 protein, as in claims 33-36 and 47-50. There is no mention of Cry2 in the specification.

Neither the instant specification nor the originally filed claims appear to provide support for the recitation of the crop producing a Cry9 protein, as in claims 31-32, 39 and 45-46. There is no mention of Cry9 in the specification.

Neither the instant specification nor the originally filed claims appear to provide support for the recitation of the crop producing a Vip3A protein, as in claims 35-37 and 49-518. There is no mention of Vip3A in the specification.

The only toxins mentioned in the context of planting a mixture of crops, each transformed with a different toxin directed to the same pest are Cry1F, Cry1A(b), Cry34/35 and Cry 3 (see pg 6, lines 8-25).

Neither the instant specification nor the originally filed claims appear to provide support for the recitation of any combinations other than Cry1F with Cry1Ab and Cry34/35 with Cry 3 in claims dependent upon claims 8 and 23. See pg 12, lines 11-18 and original claims 13 and 28.

Thus, such recitations constitute NEW MATTER. In response to this rejection, Applicant is required to point to support for the recitations or to cancel the new matter.

Applicant urges that all patents are specifically incorporated by reference (response pg 9).

This is not found persuasive. To refer everything to the specification as originally filed, ¶85 of 2008/0226753 corresponds to pg 20, lines 21-24.

Art Unit: 1638

Incorporation by reference requires a specific indication of what material is being incorporated. See *Advanced Display Systems Inc. v. Kent State University*, CAFC, 54 USPQ2d 1673, at pg 1679-1680:

To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents. See *In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement “clearly identifying the subject matter which is incorporated and where it is to be found”); *In re Saunders*, 444 F.2d 599, 602-03, 170 USPQ 213, 216-17 (CCPA 1971) (reasoning that a rejection for anticipation is appropriate only if one reference “expressly incorporates a particular part” of another reference); *National Latex Prods. Co. v. Sun Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6th Cir. 1959) (requiring a specific reference to material in an earlier application in order have that material considered part of a later application); cf. *Lund*, 376 F.2d at 989, 153 USPQ at 631 (holding that a one sentence reference to an abandoned application is not sufficient to incorporate material from the abandoned application into a new application).

Applicant urges that Cry2 and Cry9 are mentioned in US 6,023,013 and Vip3A in 5,877,012, both of which have been incorporated by reference (response pg 9).

This is not found persuasive. To refer everything to the specification as originally filed, ¶11 and ¶15 of 2008/0226753 correspond to pg 3, lines 18-31, and pg 4, line 24, to pg 5, line 8, respectively.

US 6,023,013 is cited in the specification for modified versions of Cry3Bb; it is not cited for Cry2 and Cry9. US 5,877,012 is cited in the specification for methods of expressing insect toxins in plants; it is not cited for Vip3A. There is no specific mention of incorporation of Cry2, Cry9 and Vip3A by reference. Thus, US 6,023,013 and 5,877,012 do not provide support for claims reciting Cry2, Cry9 and Vip3A.

Applicant urges that written description support is examined in view of the disclosure as filed, not a particular portion of the application (response pg 9-10).

This is not found persuasive because of the context in which the cited paragraphs are. The context is background; it not a discussion of what Applicant’s invention is.

Art Unit: 1638

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 4, 16 and 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al (2003, Nature Biotechnol. 21:1493-1497). The rejection is repeated for the reasons of record as set forth in the Office action mailed 7 January 2009. Applicant's arguments filed 4 April 2009 have been fully considered but they are not persuasive.

The claims are drawn to a method of reducing the development of resistant pests in a field of transgenic pest resistant crops, the method comprising planting a blend of two types of transgenic seed, each pesticidal to the same pest but each using a different mode of pesticidal action.

Zhao et al teach a blend of broccoli plants, wherein one plant confers resistance to diamondback moth by way of Cry1Ac and the other by way of Cry1C (paragraph spanning the columns on pg 1494; Fig 1). As there is no linkage between Cry1Ac and Cry1C resistance genes in diamondback moth (pg 1494, left column, paragraph 1), the Cry1Ac and Cry1C work via different modes of action.

Zhao et al do not teach planting a blend of seeds of the plants.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of preventing insect pests from developing resistance to Bt toxins

Art Unit: 1638

taught by Zhao et al to plant a blend of seeds. One of ordinary skill in the art would have been motivated to do so because seeds are what farmers would plant in the fields.

Applicant urges that Zhao teaches away from the claimed method because they teach that it is inferior and that other methods are preferable (response pg 11-12).

This is not found persuasive because Zhao does not teach that it should never be used. Further, one of skill in the art would use the claimed method in studies of delaying insect resistance evolution, at least as a comparison to other methods.

9. Claims 5 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al (2003, Nature Biotechnol. 21:1493-1497) as applied to claims 1, 4, 16 and 19 above, and further in view of Pershing et al (2003, US 6,551,962). The rejection is repeated for the reasons of record as set forth in the Office action mailed 7 January 2009. Applicant's arguments filed 4 April 2009 have been fully considered but they are not persuasive.

The claims are drawn to a method of reducing the development of resistant pests in a field of transgenic pest resistant crops, the method comprising planting a blend of two types of transgenic seed, each pesticidal to the same pest but each using a different mode of pesticidal action, and wherein the seed has been treated with a pesticidal agent.

The teachings of Zhao et al are discussed above. Zhao et al do not teach treating seed with a pesticidal agent.

Pershing et al teach treating seed transformed with a nucleic acid encoding a Cry3Bb protein, which is toxic to ECB and WCRW, optionally with a nucleic acid encoding a second pesticidal protein, with pesticidal agents including pyrethrins, oxadizines, chloronicotinyls,

Art Unit: 1638

nitroguanidines, triazoles, organophosphoates, pyrrols, pyrazoles, diacylhydrazines and carbamtes (column 3, line 38, to column 4, line 10; claims 8-15).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of preventing insect pests from developing resistance to Bt toxins taught by Zhao et al, to treat the seed with a pesticidal agent as described in Pershing et al. One of ordinary skill in the art would have been motivated to do so because Pershing et al teach that the chemical pesticidal treatment would reduce the chance of the pests developing resistance (column 3, line 59, to column 4, line 10).

Applicant urges that because Zhao et al teaches away from the claimed method, the rejection cannot be supported (response pg 12-13).

This is not found persuasive for the reasons indicated above.

10. Claims 14 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al (2003, Nature Biotechnol. 21:1493-1497) as applied to claims 1, 4, 16 and 19 above, and further in view of Plaisted et al (1999, US 5,990,395). The rejection is repeated for the reasons of record as set forth in the Office action mailed 7 January 2009. Applicant's arguments filed 4 April 2009 have been fully considered but they are not persuasive.

The claims are drawn to a method of reducing the development of resistant pests in a field of transgenic pest resistant crops, the method comprising planting a blend of two types of transgenic seed, each pesticidal to the same pest but each using a different mode of pesticidal action and wherein the seed is also transformed with an EPSPS gene.

The teachings of Zhao et al are discussed above. Zhao et al do not teach do not teach seed transformed with an EPSPS gene.



Art Unit: 1638

Plaisted et al teach transforming plants with a Cry1Ab gene or VIP3 (now known as the VIP3A) gene, and an EPSPS gene (column 10, line 59, to column 11, line 52).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of preventing insect pests from developing resistance to Bt toxins taught by Zhao et al to also include an EPSPS gene in the seed, given advantages of herbicide resistance touted by Plaisted et al (column 9, line 61, to column 10, line 16).

Applicant urges that because Zhao et al teaches away from the claimed method, the rejection cannot be supported (response pg 13).

This is not found persuasive for the reasons indicated above.

11. Claims 2-3, 6-7, 17-18, 21-22, 31-37 and 45-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al (2003, Nature Biotechnol. 21:1493-1497) as applied to claims 1, 4, 16 and 19 above, and further in view of each of Crickmore et al (1998, Microbiol. Mol. Biol. Rev. 62:807-813), Plaisted et al (1999, US 5,990,395), Pershing et al (2003, US 6,551,962) and Narva et al (WO 97/40162), taken with the evidence of the instant specification. The rejection is repeated for the reasons of record as set forth in the Office action mailed 7 January 2009. Applicant's arguments filed 4 April 2009 have been fully considered but they are not persuasive.

The claims are drawn to a method of reducing the development of resistant pests in a field of transgenic pest resistant crops, the method comprising planting a blend of two types of transgenic seed, each pesticidal to the same pest but each using a different mode of pesticidal action and wherein the seed is also transformed with nucleic acids encoding specific Bt toxins.

Art Unit: 1638

The teachings of Zhao et al are discussed above. Zhao et al do not teach nucleic acids encoding Cry1F, Cry3, Cry1Ab, Cry2, Cry34Aa1 and Cry35Aa1 or VIP3, nor do they teach mosaics in which one or both seed types of transformed with more than one toxin encoding nucleic acid.

Crickmore et al teach numerous Cry proteins, including Cry1F, Cry3, Cry1Ab and Cry2 proteins (Table 1).

Narva et al teach nucleic acids encoding toxins now known as Cry34Aa1 and Cry35Aa1, which confer resistance to Western corn rootworm (pg 26, lines 10-14, 23-27).

Pershing et al teach treating seed transformed with a nucleic acid encoding a Cry3Bb protein, which is toxic to ECB and WCRW, optionally with a nucleic acid encoding a second pesticidal protein, with pesticidal agents including pyrethrins, oxadizines, chloronicotinyls, nitroguanidines, triazoles, organophosphoates, pyrrols, pyrazoles, diacylhydrazines and carbamates (column 3, line 38, to column 4, line 10; claims 8-15).

Plaisted et al teach transforming plants with a Cry1Ab gene or VIP3 gene (now known as VIP3A), and an EPSPS gene (column 10, line 59, to column 11, line 52).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of reducing the development of resistant pests in a field of transgenic pest resistant crops taught by Zhao et al, to use nucleic acids encoding the Cry toxins described in each of Crickmore et al, Plaisted et al, Pershing et al and Narva et al. One of ordinary skill in the art would have been motivated to do so because selection of one endotoxin over another would be an obvious step in the optimization of a seed/toxin combination that is

Art Unit: 1638

best suited to a particular environmental setting. The instant specification teaches that Cry1F, Cry1Ab, Cry 34/35 and Cry3 all confer resistance to ECB and WCRW (pg 6, lines 17-25).

Applicant urges that because Zhao et al teaches away from the claimed method, the rejection cannot be supported (response pg 14).

This is not found persuasive for the reasons indicated above.

Applicant urges that Crickmore teaches over 100 different Cry proteins, with others disclosed in the other references; this would result in trying 10,000 combinations, as the prior art does not provide guidance for which combinations are likely to be successful (response pg 14-15).

This is not found persuasive because one of skill in the art would select a toxin combination based on the desired target pests. Thus, one would not be trying all 100 different Cry proteins taught in Crickmore, but only the subset that targets the pests of interest. As ECB and WCRW are common pests of the economically important crop, corn, one of skill in the art would be motivated to choose toxins that are effective against these pests.

### ***Conclusion***

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, Ph.D., whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

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Art Unit: 1638

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July 28, 2009

/Anne R. Kubelik/

Primary Examiner, Art Unit 1638